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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/645,202

08/21/2003

Paul C. McAfee

04-005-US1

7244

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7590

09/21/2007

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EXAMINER

SHAFFER, RICHARD R

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

09/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/645,202	Applicant(s) MCAFFEE, PAUL C.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/7/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 2nd, 2007 has been entered.

Drawings

The amended drawings filed on July 2nd, 2007 are acknowledged by the examiner. However, several additional deficiencies have been determined.

The drawings are objected to for the following issues:

- 1) A reference character "12" as described in the specification is not found in the amended drawings.
- 2) "2" in Figure 7A is not referring to the same structure as found in Figures 1 and 2.
- 2) The description in paragraph 0045 states in regard Figures 6a and 6b that "10" is slotted and "9" is opposing c-clamps when the brief description states both as being "one-piece non-slotted." It is clear that 6a is non-slotted and 6b has opposing c-clamps.
- 3) The description of Figures 4 and 5 state fully constrained and partially constrained options. This is inaccurate since Figure 4 merely shows a cross-linking member with Figure 5 showing where such a member is placed in the spinal rod system.
- 4) In general, applicant is inconsistent in depicting his device with Figures 1, 2, 5, 11a and 11b showing a hollow cylindrical sleeve over the spinal rod (3) stating the inner and outer surfaces are different bearing and therefore of different material. Then in Figures 3, 4, 6a, 6b and 7a-10b showing that the outer bearing surface is actually the metal associated with the spinal rod connector (whether for pedicle or cross-linking two spinal rods) having an UHMWPE insert 17.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to for the same reasons given in reasons 1-4 of the drawing objections. The specification fails to clarify the confusion therefore leading one to be unsure what the actual invention is as well as if the description of the drawings even corresponds to them.

Claim Objections

Claims 25-34 and 36 are objected to because of the following informalities:

Independent claims 25, 30, 34 and 36 set forth a "motion preserving spinal implant system" which among other elements comprises a "motion preserving implant." There is no antecedent basis for such language as found in the specification, and further one would not consider any portion of the system an implant without the remaining components since the device would not "preserve motion" without being the system. It is recommended that applicant use different language than "motion preserving implant," but may continue to the overall system as being motion preserving.

Also, claim 25 recites "a dampener" after reciting a sleeve. The specification states that both the sleeves and bumpers act as dampeners. It is recommended different language be utilized for "dampener" in claim 25 to avoid confusion with the already recited "sleeve." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites the limitation "the rod portion" in lines 1 and 2. It is indefinite which rod portion (the first or second) that it's being coupled to. Applicant also fails to distinctly define claim 30 due to reciting a "second motion preserving implant" with language that overall appears applicant is reciting another sleeve in tandem with a bumper and bone anchors yet somehow is a "second implant" with it's own "rod portion" which the rod as always depicted as a single rod passing through the device. Applicant is encourage to avoid the terminology "motion preserving implant" and to more clearly define the claim to correspond with what has been disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmotzer (US Patent 6,290,700) in view of Rivard (US Patent 5,413,576).

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Schmotzer discloses (**Figures 1-4**) a system comprising: at least two bone anchors (**10**); a titanium (**Column 4, Lines 27-30**) longitudinal spinal rod (**15**); at least two sleeves (**16, Figure 2**) are located about a portion of the rod; at least one bumper (**22**) is located between two sleeves (**16**); and there is inherently a gap between the bumper and sleeve during a flexion (the screws **10** would separate allowing sleeves **16** and bumper **22** to separate) configuration and no gap during an extension configuration (which is already depicted in the Figures).

Schmotzer fails to disclose the use of a UHMWPE internal bearing layer on the sleeves (**16**). Rivard teaches (**Column 4, Lines 45-46**) that a polyethylene liner (**76**) is used to reduce friction between the sliding of the rod and clamping components. It would have been obvious to one having ordinary skill in the art to use a polyethylene liner (such as UHMWPE) in order to reduce friction in order to ensure the device would not 'catch' during physiological movement as well as to reduce wear in the spinal stabilization system of Schmotzer.

Claims 25-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmotzer in view of Rivard and in further view of Fiz (US Patent 6,083,226).

Schmotzer in view of Rivard disclose and teach all of the claimed limitations except for the use of offset connectors, a locking element to fix the offset connectors to the bone anchor, the bone anchors having polyaxial heads and that at least three bone anchors are included in the system.

Fiz teaches (**Figures 1-10**) a polyaxial offset connector (**8**) spanning more than two vertebral bodies (**Figures 1-3**) and a locking element (**14**) to fix the offset connector

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(8) to a bone anchor (9). It is well known that polyaxial connections allow for easier assembly by attaching a screw in one orientation but orientating the head along the desired path for the spinal rod. Offset connectors benefit in the same sense that if a surgeon would rather fix the bone anchor away from the location the rod will pass, the offset connector will be able to still align the rod receiving portion with the desired path along the spine. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide combinations of offset polyaxial connectors with a locking element (to connect to the bone anchor) as well as standard mono-axial (without offset connectors) in order to provide a surgeon with a plurality of options during surgery in order to achieve the quickest yet most stable spinal stabilization possible.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
September 15th, 2007



EDWARD C. ROBERT
SUPERVISOR, PATENT EXAMINER